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PCT/EP2003/008196

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LINO694PWO	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/008196	International filing date (day/month/year) 25 July 2003 (25.07.2003)	Priority date (day/month/year) 26 July 2002 (26.07.2002)
International Patent Classification (IPC) or national classification and IPC A61F 2/38		
Applicant WALDEMAR LINK GMBH & CO. KG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 03 February 2004 (03.02.2004)	Date of completion of this report 10 November 2004 (10.11.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

translation

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/008196

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages _____ 1-8 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____ 1-4 _____, filed with the letter of _____ 06 July 2004 (06.07.2004)
- ☒ the drawings:
 pages _____ 1 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-4	YES
	Claims		NO
Inventive step (IS)	Claims	1-4	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-4	YES
	Claims		NO

2. Citations and explanations

Reference is made to the following documents:

- D1: EP-A-0 420 460 (UNIV LONDON), 3 April 1991 (1991-04-03)
D2: DE 41 02 509 A (BREHM PETER), 30 July 1992 (1992-07-30)

1. Claim 1 fails to meet the requirements of PCT Article 6 because the subject matter for which protection is sought does not appear to be clearly defined. The claim seeks to define its subject matter by reference to the result which is to be achieved, but in doing so merely states the problem addressed without specifying the technical features needed in order to achieve this result. The claim specifies that when rotation occurs each of the two condyle sliding surfaces remains in contact with the associated tibia sliding surface in front of and behind the normal contact area. For a person skilled in the art trying to achieve maximum pressure reduction on the sliding surfaces this is obvious and desirable, but the claim fails to state which technical feature is responsible for the contact in front of and behind the normal contact area.

- 1.1 The problem of interest is solved by the technical feature whereby (see the description, page 7, lines 21 to 27) "the shape of the tibia sliding surfaces is such that they have the same profile as the condyle sliding surfaces along arcs

around the axis of rotation in an intersecting plane that contains the said axis of rotation".

The incorporation of such a feature in claim 1 would overcome the above objection relating to clarity.

2. The following comments are based on the assumption that a feature such as that referred to in point 1.1 above will be added to claim 1.

- 2.1 Document D2, which is considered to be the prior art closest to the subject matter of claim 1, discloses the following (the references in parentheses are to D2):

a knee prosthesis with a femoral prosthesis part (1) which forms a pair of condyle sliding surfaces (5), a tibial part (2) with tibia sliding surfaces (9) that interact with the condyle sliding surfaces (5), and a coupling part (10) which connects the femoral and tibial parts (1, 2) in such a way as to allow rotation about an axis of rotation (12) running approximately parallel to the shin bone, wherein the tibia sliding surfaces have a normal contact area (14) that interacts with the associated condyle sliding surfaces (5) when the femoral and tibial parts (1, 2) are in the same anteroposterior orientation, and slope upwards in front of normal contact area (14) with a radius of curvature.

The subject matter of independent claim 1 (modified as outlined in point 1.1 above) differs

in that the tibia sliding surfaces slope upwards in front of normal contact area (14) with a radius of curvature that is significantly greater than the radius of curvature of the part of the condyle sliding surface that interacts with the tibia sliding surface, and in that the shape of the tibia sliding surfaces is such that they have the same profile as the condyle sliding

surfaces along arcs around the axis of rotation in an intersecting plane that contains the said axis of rotation.

2.2 The problem addressed by the invention can therefore be seen as that of ensuring that when rotation occurs each of the two condyle sliding surfaces remains in contact with the associated tibia sliding surface in front of and behind the normal contact area.

2.3 This problem is solved by the tibia sliding surfaces with the form described in the modified claim 1 (see point 1.1 above). The solution is not obvious because it is not suggested by any of the documents cited in the search report.

Taking into account the cited documents, a version of claim 1 that is modified as outlined in point 1.1 above would meet the requirements of PCT Article 33(1); that is, it would appear to be novel, inventive and industrially applicable.

3. It is noted that the original version of claim 1 is not novel over the prosthesis disclosed in D1. The prosthesis according to D1 has all the technical features of claim 1, and the femoral and tibial parts of the prosthesis can be rotated against each other in the way specified in claim 1 (see in particular column 4, lines 32 to 36 and 53 to 58, and figure 4).

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Patent claims

1. A knee prosthesis with a femoral prosthetic part (1) which forms a pair of condylar sliding surfaces (5), with a tibial part (2) which has tibial sliding surfaces (9) cooperating with the condylar sliding surfaces (5), and also a coupling part (10) which connects the femoral and tibial parts (1, 2) to one another so that they can rotate about a rotation axis (12) approximately parallel to the tibia, the tibial sliding surfaces having an area (14) of normal contact which, when the femoral and tibial parts (1, 2) have the same anteroposterior alignment, cooperates with the associated condylar sliding surface (5), and, in front of the area of normal contact (14), they slope upward with a radius of curvature much greater than the radius of curvature of that part (13-15) of the condylar sliding surface (5) cooperating with the tibial sliding surface, characterized in that the tibial sliding surfaces (9) also slope upward behind the area (14) of normal contact in such a way that, in the event of rotation, each of the two condylar sliding surfaces (5) remains touching the associated tibial sliding surface (9) in front of or behind the area (14) of normal contact.
2. The prosthesis as claimed in claim 1, characterized in that the rotation axis (12) is fixed in relation to the femoral and tibial prosthesis parts (1, 2) in the anteroposterior direction.

AMENDED PAGE

3. The prosthesis as claimed in claim 1, characterized in that the rotation axis (12) is displaceable in relation to the femoral or tibial prosthesis part (1, 2) in the anteroposterior direction.
4. The prosthesis as claimed in one of claims 1 through 3, characterized in that the radius of curvature of that part (13-15) of the condylar sliding surface (5) cooperating with the tibial sliding surface (9) is substantially constant in the flexion plane.